

Application No. 10/509,416
Amdt. Dated: June 4, 2008
Reply to Office Action Dated: April 11, 2008
Customer No.: 24737

REMARKS/ARGUMENTS

The Examiner is thanked for the final Office Action dated April 11, 2008. The status of the application is as follows:

- Claims 1-10 are pending, and claim 9 has been amended;
- Claims 11-20 are withdrawn from further consideration as being directed to a distinct invention;
- Claim 9 is rejected under 35 U.S.C. 112, second paragraph; and
- Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golasarsky (US 5,891,044) in view of Segalowitz (US 5,307,818).

The rejections are discussed below.

The Rejection of Claim 9 under 35 U.S.C. §112, second paragraph

The Office rejected claim 9 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office contends that it is unclear what constitutes a high priority alarm and what prior art elements do or do not fall within the boundaries of this limitation. In response, claim 9 has been amended to delete the limitation directed to a high priority alarm, rendering the rejection moot.

The Rejection of Claims 1-10 under 35 U.S.C. §103(a)

Claims 1-10 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Golasarsky in view of Segalowitz. This rejection should be withdrawn because Golasarsky in view of Segalowitz does not teach or suggest all of the limitations of the subject claims and, therefore, fails to establish a *prima facie* case of obviousness with respect to the subject claims.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, (CCPA 1974). MPEP §2143.03.

Independent claim 1 is directed towards a wearable heart monitoring system for monitoring of a cardiac arrhythmia. The wearable heart monitoring system includes, *inter alia*, a real-time evaluator that measures and analyzes a histogram of a temporal distribution of an interval between successive corresponding characteristic peaks in an ECG spectrum during a plurality of successive heart cycles, and an alarm generator that generates an alarm based on the analysis of the histogram. The Office contends that these claim aspects would have been obvious to one of ordinary skill in the art based upon Golasarsky in view of Segalowitz. However, Golasarsky in view of Segalowitz does not teach or suggest such claim aspects.

Golasarsky teaches an apparatus and method for determining a user's stress state and/or a distress condition. The apparatus for use with the method is disclosed in col. 8, lines 4-20, as a module strapped to the user's wrist comprising a passive SOS time interval sensor, a radio means for conveying recorded time intervals, a motion sensor, means responsive to the motion sensor to distinguish a physical state of the user, a galvanic skin sensor, and a means responsive to the galvanic skin sensor to distinguish between states of connectivity. The stress state and/or distress condition is detected from simple parameters derived from the recording of a plurality of durations of successive Time Intervals between the Start of Systole (SOS)(measured in pressure) to the Start of Systole in successive heart beats (see Fig. 1B). The Time Intervals are detected by the SOS time interval sensor 80 (see Figs. 3 and 5).

Segalowitz discloses a method and system for electrocardiographic monitoring. In an embodiment, the system comprises a precordial strip assembly having six conductive elements V_1 - V_6 (see Figures 8 and 10a). The precordial strip is placed over the precordium of a patient so that the conductive elements can detect electrical signals generated when the heart muscle contracts. The method and system in the various disclosed embodiments also includes other conductive elements for connection to the skin of the patient on selected parts of the patient's body. For example, in Figures 1, 8,

and 9 there are additional conductive elements connected to one or more of the left arm, right arm, right leg and left leg of a patient. In Figures 17, 18, 22 and 23, disclosed is a precordial strip having the six conductive elements V_1 - V_6 and the additional conductive elements for connection to the precordium of a patient. The additional conductive elements correspond to the traditional precordial limb detection points necessary for measuring ECG signals. In Figures 25 and 26, disclosed is a precordial strip having the six conductive elements V_1 - V_6 and the additional conductive elements located in proximity thereto for connection to the precordium of a patient. The conductive elements V_1 - V_6 and the additional conductive elements are connected to suitable electrocardiograph (ECG) equipment which records the electrical signals.

The Office concludes that it would have been obvious to one of ordinary skill in the art to add the electrodes V_1 - V_6 of Segalowitz to the watchband of Golasarsky in order to acquire ECG data as suggested in Golasarsky. However, applicant respectfully traverses this conclusion.

In this regard, if the conductive elements V_1 - V_6 of Segalowitz were to be added to the watchband in Golasarsky as the Office has proposed, the conductive elements V_1 - V_6 of Segalowitz could not acquire ECG data of the heart as is required by claim 1. In order to acquire the ECG data, the conductive elements V_1 - V_6 must contact the skin of the patient in a location suitable to detect heart signals. One such location has been found to be the patient's precordium. The additional conductive elements must also be in contact with the patient's skin at other selected points on the patient's body. In Segalowitz, the precordial strip having the six conductive elements V_1 - V_6 is placed over the precordium of the patient for this reason (See col. 6, lines 52-67; Abstract). If the Office believes otherwise, applicant respectfully requests that the Office provide evidence in support of this belief. If the conductive elements V_1 - V_6 of Segalowitz were to be added to the wrist module of Golasarsky, the conductive elements V_1 - V_6 would not be positioned on the patient in a location suitable to obtain the required heart signals. The patient's wrist is not a suitable location to detect heart signals.

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Moreover, Golasarsky does not teach or suggest acquiring ECG data as the Office contends (col. 2, lines 39-55). As previously discussed, Golasarsky discloses detecting a user's stress state with a SOS time interval sensor 80 positioned in a module strapped to the user's wrist. The SOS time interval sensor 80 senses changes in pressure between Time Intervals in successive heart beats. The Time Interval data is not the same as ECG data.

Accordingly, applicant respectfully submits that claim 1 is allowable, and the rejection of claim 1 should be withdrawn.

Claims 2-7 depend from claim 1 and are allowable at least by virtue of their dependency upon an allowable base claim.

Independent claim 8 is directed towards a method for alerting a patient for a substantial probability of a cardiac arrest event for use with an apparatus substantially as claimed in claim 1. As such, the discussion above regarding claim 1 applies *mutatis mutandis* to claim 8, and this rejection should be withdrawn.

Claims 9-10 depend from claim 8 and are allowable at least by virtue of their dependency upon an allowable base claim.

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Conclusion

In view of the above, it is submitted that the subject claims distinguish patentably and non-obviously over the prior art of record. An early indication of allowability is earnestly solicited.

Respectfully submitted,

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